SV2
ID#_____
Date __ __/__ __/__ __ __ __

Eligibility Questionnaire

NAME:_____
(First) (Last)

Please review and answer all of the questions on this form. Indicate your answers by placing an "x" in the appropriate box. Depending upon your answers, some of the questions may be skipped.

At your next visit, please return this form and also bring in all of the medications you currently take. Bring in not only prescription medications, but also any non-prescription medications (including vitamins and other food supplements) that you take on a regular basis.

Thanks very much for your cooperation.

	Yes	No	Unsure	Comments
1. Have you ever had any of the following?				
a. Stroke	☐ 1	☐ 2	☐ 3	_____
b. Heart attack	☐ 1	☐ 2	☐ 3	_____
c. Heart failure	☐ 1	☐ 2	☐ 3	_____
d. Angina	☐ 1	☐ 2	☐ 3	_____
e. Coronary bypass surgery or angioplasty	☐ 1	☐ 2	☐ 3	_____
f. Prescription for nitroglycerin tablets for heart pain	☐ 1	☐ 2	☐ 3	_____
2. Do you have asthma or another chronic obstructive lung disease, such as chronic bronchitis, emphysema or COPD, etc.?	☐ 1	☐ 2	☐ 3	_____
If yes, within the past 6 months have you: a. Changed breathing medications or increased the dosage of your breathing medication?	☐ 1	☐ 2	☐ 3	_____
b. Been to the emergency room or been hospitalized for breathing problems?	☐ 1	☐ 2	☐ 3	_____
3 Have you ever had cancer?	☐ 1	☐ 2	☐ 3	_____
If yes, was it: Active within the past 6 months or treated with radiation or chemotherapy within the past 6 months?	☐ 1	☐ 2	☐ 3	_____

ID #_____

	Yes	No	Unsure	Comments
4. Have you ever had any of the following stomach or gastrointestinal (GI) conditions?				
a. Chronic GI disorder (such as Inflammatory Bowel Disease, Crohn's Disease, malabsorption)	☐ 1	☐ 2	☐ 3	_____
b. Colostomy or history of bowel resection (removal)	☐ 1	☐ 2	☐ 3	_____
5. Have you ever had kidney failure, a kidney transplant, or dialysis?	☐ 1	☐ 2	☐ 3	_____
6. Do you have any medical conditions or special dietary requirements that might interfere with your ability to eat study foods or attend the clinic for at least one meal a day five days each week?	☐ 1	☐ 2	☐ 3	_____
7. Do you regularly take any of the following?				
a. Tums	☐ 1	☐ 2	☐ 3	_____
b. Rolaids	☐ 1	☐ 2	☐ 3	_____
c. Other non-prescription antacid	☐ 1	☐ 2	☐ 3	_____
d. Vitamins	☐ 1	☐ 2	☐ 3	_____
e. Calcium, magnesium or potassium supplements	☐ 1	☐ 2	☐ 3	_____
f. Salt substitutes	☐ 1	☐ 2	☐ 3	_____
g. Over the counter products or medications containing sodium (see attached list)	☐ 1	☐ 2	☐ 3	_____
h. Metamucil	☐ 1	☐ 2	☐ 3	_____
8. *If you checked yes next to any of the medicines in question 7*, would you be willing to stop taking them during the study?	☐ 1	☐ 2	☐ 3	_____
9. Have you taken any medications to control your blood pressure in the past 3 months?	☐ 1	☐ 2	☐ 3	_____
10. Do you regularly take any of the following medications?				
a. Steroid or corticosteroid pills	☐ 1	☐ 2	☐ 3	_____
b. Cholestyramine or colestipol	☐ 1	☐ 2	☐ 3	_____
c. Breathing medicines other than inhalers	☐ 1	☐ 2	☐ 3	_____
d. Dilantin or phenytoin	☐ 1	☐ 2	☐ 3	_____
e. Digitalis	☐ 1	☐ 2	☐ 3	_____
f. Lithium	☐ 1	☐ 2	☐ 3	_____
g. Insulin	☐ 1	☐ 2	☐ 3	_____
h. Diet pills/weight loss medication (see attached list)	☐ 1	☐ 2	☐ 3	_____

ID#_____

	Yes	No	Unsure	Comments
11. Do you regularly take medications for psychological or emotional problems?	☐ 1	☐ 2	☐ 3	_____
If yes, have you changed medications or the dosage of the medications you take within the past 6 months?	☐ 1	☐ 2	☐ 3	_____
12. Do you currently use smokeless tobacco products (e.g. chew, snuff)?	☐ 1	☐ 2	☐ 3	_____
13. Are you currently taking any lipid lowering medications on the attached list.	☐ 1	☐ 2	☐ 3	_____
If yes, have you changed your dosage in the past month?	☐ 1	☐ 2	☐ 3	_____
14. Are you planning to leave the area within the next year?	☐ 1	☐ 2	☐ 3	_____

15. On average, how many drinks of alcohol do you have in a week?
If you don't drink alcohol, enter 0.
(one drink = 1 can of beer or 1 glass of wine or 1 shot of liquor)

_____ drinks per week

For women only

16. Are you pregnant, planning to become pregnant or breast feeding?	☐ 1	☐ 2	☐ 3	_____

Over-the-counter Drugs and Products Containing Sodium (Question 7, part g)

Baking soda toothpaste
Baking soda for upset stomach
Alka Seltzer
Bisodol powder
Bromo-seltzer

Weight-loss Drugs (Question 10, part h)

This list includes some but not all the over the counter products found in drug stores or health food stores. Please respond yes if you use any product for this purpose.

Generic name	Brand name
Benzphetamine	Didrex
dexfenfluramine	Redux
diethylpropion	Tenuate
	Tepanil
fenfluramine	Pondimin
phentermine	Adipex, Fastin, Ionamin, Obenix, Oby-Cap, Oby-Trim
	Pro-Fast, Zantril
fenfluramine/phentermine	Fen/Phen
mazindol	Sanorex
	Mazanor
phendimetrazine	Plegine, X-trozine, Bontril, Prelu-2
phenmetrazine	Preludin
phenylpropanolamine	Dexatrim, Accutrim
d-amphetamine	Dexadrine, Dextrostat
methamphetamine	Desoxyn
orlistat	Xenical
sibutramine	Meridia

Lipid-lowering drugs that are exclusionary only if the dosage has changed (Question 13)

Generic name	Brand name
lovostatin	Mevacor
pravastatin	Pravachol
simvastatin	Zocor
fluvastatin	Lescol
atorvastatin	Lipitor
nicotinic acid	Niacin, Slo-Niacin, Niacor, Nicobid, Niacinamide,
	Nicotinamide
gemfibrozil	Lopid
clofibrate	Atromid-S
bizafibrate	Bezalip
dextrothyroxine sodium	Choloxin
probucol	Lorelco

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OFFICE USE ONLY - DO NOT GIVE TO PARTICIPANT

List all participant prescription medications, over-the-counter medications, vitamins and other food supplements here:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____

17. Is the participant taking any of the following class of medications? **Yes** **No**

a. lipid lowering medications (see attached list and Q10b, Q13)-------	☐ 1	☐ 2
If yes, are they automatically exclusionary? ----------	☐ 1	☐ 2
If no, is the dosage unstable? ----------	☐ 1	☐ 2
b. weight loss medications (see attached list)** ----------	☐ 1	☐ 2
c. over the counter products not allowed (see attached list)* ----------	☐ 1	☐ 2
d. estrogen replacement therapy medications ----------	☐ 1	☐ 2
e. any other excluded medications----------	☐ 1	☐ 2

* If participant is willing to stop medications, code response as "no".

** Participant may stop these medications and be screened for another cohort. If the product is not on the attached list, make a copy of the ingredients and have the clinician review

Clinician signature:_____

Reviewed by (staff ID): _____
Entered by (staff ID):_____

Administration and Coding Instructions for Medical Eligibility Questionnaire

General Coding Instructions

1) Use correct version of form. The correct version will always be on the file server.
2) Use either black or blue pen on all forms, not pencil.
3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data..
6) Do not obliterate or erase any entry of the respondent.
7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, along side the corrected entry, write your initials, the date of the correction and a note about why the correction was made. (e.g., RL, 7/30/97, incorrect ID)
8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
9) Check all lead-in questions for correct skip patterns.
10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered..

Eligibility Questionnaire

This questionnaire will begin the process of screening applicants for a variety of medical conditions and personal habits that would make participants ineligible. Some of these conditions/habits could interfere with the study by obscuring the effects of the study diet. Others might make it harmful or unwise for an individual to participate. The following information is intended to help you assist applicants in providing accurate answers to these questions. When uncertainty remains after reviewing a question with these instructions, please indicate this on the questionnaire so that further review may be undertaken by a study clinician.

Ultimately, all "Unsure" responses must be resolved and coded either "Yes" or "No".

This form will typically be completed by the participant at home between the SV1 and SV2 visits. When distributing the form to the participant, be sure to remove the last page ("for office use only" section) and store it in the participant's study chart. The participant should receive page 4, however, which lists specific medications and products that are referred to in three of the questions.

In addition, remind the participant to bring all of his/her medications, including nonprescription medications such as vitamins, allergy preparations, and food supplements, with them to his/her next visit. Finally, review the instructions for completing the form with the participant..

Participant and Visit Identifying Data

ID # - Clearly enter the ID number that has been assigned, and check to be sure the numbers and letters have been copied correctly. If an ID number has not been assigned yet, leave blank and fill in later.

Date - Clearly enter the date when this form **is reviewed with the participant**. If the form is completed at home, the participant should be instructed to leave it blank. It will be filled in at the SV2 visit. As appropriate, use leading zeros for numbers less than 10 (08/14/1994 represents the date of August 14, 1994).

Q1a-f. These questions are intended to screen for cardiovascular disease other than hypertension. An individual with only hypertension should answer No to each question.

If any question is answered Yes, participant is ineligible for the study.

Q2. This question is intended to screen for individuals with obstructive airways disease that is unstable and thus could interfere with the study. A person who is currently being treated for asthma or COPD, or who has been treated for one of these conditions as an adult, should answer Yes. If an individual has a history of childhood asthma only, with no recurrences as an adult, they may answer No and skip to question 3. If Yes or uncertain, proceed to second part of question.

The second part of this question refers to the past six months. It is important to find out if there has been a worsening in the individual's asthma or COPD, and that should guide the answers to these questions. Any change in medication, including an increase in dose, should be noted as a Yes for Q2a. A decrease in dose of a regular medication, if no other changes have been made, is not significant and should be answered as No. A refill does not constitute a change in medication.

An asthmatic or COPD episode that resulted in a visit in the last six months to the emergency room, urgent/immediate care clinic, or an admission to the hospital should be noted as a Yes to Q2b.

If Yes to either Q2a or Q2b, participant is ineligible.

Q3. Answer Yes to initial inquiry if a person has ever had a diagnosis of cancer. If there is no history of cancer, answer No and skip to question 4.

Inactive cancers are those which have (1) been in remission for over six months or were removed over six months ago AND (2) have not resulted in any further treatment within the past six months. Active cancers include those that have been present within the past six months OR which have required treatment within the past six months. For instance, a woman with breast cancer who had the tumor removed eight months ago, but who was treated with chemotherapy that ended four months ago, would answer Yes to the question "was (your cancer) active in the past six months?"

If Yes to the second part of question 3, participant is ineligible.

Q4. This question is intended to ascertain the presence of a chronic GI disorder that could interfere with bowel function (absorption, fluid and mineral balance). Acute infectious disorders are not of significance and need not be noted (answer No if no other problems present).

The "chronic GI disorders" of interest include those listed and any other that could interfere with bowel function. Answer Unsure if a question arises as to the significance of a condition not listed and refer it to a study clinician after the visit.

Surgery that could influence absorption or fluid and mineral balance should be indicated by answering Yes to the question about colostomy or bowel resection. Minor surgery, such as polyp removal, localized removal of a portion of the colon, or hemorrhoidectomy, is not important. An individual with these minor procedures but no other surgery may answer No.

If yes to either Q4a or Q4b, participant is ineligible.

Q5. This question is for documentation purposes only.

Q6. If Uncertain, list condition in comment field and refer to a study clinician after the visit.

If Yes, the participant is ineligible.

Q7-8. If yes to any item in a - h, Q8 should be answered.

If Q8 is answered No, participant is ineligible.

Q9. If the participant has taken blood pressure medications within the past three months, this question should be answered Yes. If this question is answered Yes, further exploration can be done to determine eligibility using the Blood Pressure Medication Follow Up form (# 132). The new eligibility requirements are that participants must be off blood pressure medications at least three months prior to randomization and one month prior to their SV1. Do NOT enter form #6 until eligibility is resolved on form # 132.

Q10. If Yes to any of items a - h, participant is ineligible. If the answer to h (diet pills/weight loss medications) is yes, the participant may be screened for a subsequent cohort if they go off the medication. Participant must be off diet pills/weight loss medications 21 days prior to SV1.

Q11. This question is intended to identify individuals who are taking unstable doses of psychotropics and/or phenothiazines. If Q11 is answered Yes, ask the second part of the question.

If Yes to the second part of Q11, participant is ineligible. Participants should be on a stable dose of psychotropics for 6 months prior to SV1.

Q12. If Yes, participant is ineligible.

Q13. This question is intended to identify individuals who are taking unstable doses of otherwise permissible lipid lowering medications. If Q13 is answered Yes, ask the second part of the question.

If Yes to the second part of Q13, participant is ineligible. Participants should be on a stable dose of otherwise permissible lipid lowering medications for one month prior to SV1

Q14. If Yes, participant is ineligible.

Q15. If participant consumes 15 or more drinks per week, he/she is ineligible. Participants who do not drink alcohol should enter zero.

Q16. This is completed only by women. If Yes, participant is ineligible.

OFFICE USE ONLY SECTION:

This page of the form should <u>not</u> be handed to the participant. They receive only the first four pages.

Medication Information

Participants are required to bring in <u>all</u> of their medications when they return/complete this form. If they fail to do so, a staff person needs to call them at home to obtain the information.

<u>All</u> medications taken should be listed. Please emphasize the importance of including non-prescription medications such as vitamins, food supplements, and allergy preparations in this list. Medications taken sporadically or on an "as needed" basis should also be included.

This review is done to ensure that any exclusionary medications have not been overlooked by the participant. If the participant is taking any medications, of if any box is checked unsure on pages 1-3, a clinician must review the form and sign the bottom of page 5 in order for the participant to continue participating in the study.

Q17. This is included as a prompt to facilitate the review of the medications. If any shaded boxes are checked, the participant is ineligible.

The staff person reviewing the form with the participant should write in his/her staff ID # at the bottom of page 5.

If any of the shaded boxes on this form are checked, the participant is ineligible.

Medications **ALLOWED** during DASH2.

Medical condition or symptom	
Aches and pains	Tylenol Aspirin Ibuprofen (but not within 48 hours before BP measurement)
Indigestion	Nephrox Amphogel
Cold/flu/allergy	Tylenol, Extra strength tylenol Chlortrimeton Benadryl Hismanal Seldane Tavist Afrin, otrivin or Ayr nasal spray Robitussin (NOT Robitussin DM) Claritin Beconase nasal spray
Constipation	Correctol Senokot
Infections	Antibiotics
Hormones	Estrogen and progesterone (but don't start these meds or change dose during feeding)
Other	Lactaid Beano

If you want to take any other medication, you must first discuss it with DASH2 study personnel. Many medications can interfere with the DASH2 study, so please ask first!

Estrogen replacement therapy drugs

Generic name	Brand name
conjugated estrogen	Premarin Prempro Milprim PMB
estradiol	Estrace Climara Vivelle
extradiol patch	Estraderm
medroxyprogesterone acetate	Provera
chlorotrianisene	Tace
diethylstilbestrol	diethylstilbestrol
est estrogens and methyltes	Estratest
esterified estrogens	Menest, Estratab
estradiol & testosterone	Depo-Testadiol
estradiol cypionate	Depo-estradiol Estradiol
estradiol val & test	Deladumone
estradiol valerate	Delestrogen Estradiol
estrone	Theelin Estrone
estropipate	Ogen Ortho-Est
estinyl estradiol	Estinyl Feminone
quinestrol	Estrovis